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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,216	04/21/2005	Michio Ishibashi	2005_0275A	2843

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WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
JEAN-LOUIS, SAMIRA JM	
ART UNIT	**PAPER NUMBER**
4173	

MAIL DATE	DELIVERY MODE
10/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,216	ISHIBASHI, MICHIO	
	Examiner	Art Unit	
	Samira Jean-Louis	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,17 and 21-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *16-17 and 21-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Group I, claim 16 is drawn to a method for screening a compound which is able to prevent, mitigate or treat renal **glomerular** lesions, which comprises measuring a promoting action of a compound to be tested on the induction of regeneration-promoting macrophages and lymphocytes caused by contact of human peripheral blood mononuclear cells (PBCs) **with a lipopolysaccharide**.

II. Group II, 17 is drawn to a method for screening a compound which is able to prevent, mitigate or treat renal **tubulointerstitial** lesions, which comprises measuring a promoting action of a compound to be tested on the induction of regeneration-promoting macrophages and/or lymphocytes caused by contact of human peripheral blood mononuclear cells **with mitomycin-treated** human peripheral blood mononuclear cells.

III. Group III, claim 21 is drawn to a method for suppression and/or regeneration of sclerotic lesions, which comprises administering a compound, which preferentially increases regeneration-promoting macrophages to a patient.

IV. Group IV, claims 22-23 is drawn to a therapeutic method for **renal glomerular** lesions, which comprises administering a pharmaceutical comprising a compound, which promotes induction of regeneration-promoting macrophages to a patient.

V. Group V, claims 24-25 are drawn to a therapeutic method for **renal tubulointerstitial** lesions, which comprises administering a pharmaceutical comprising a compound, which promotes induction of regeneration-promoting macrophages to a patient.

VI. Group VI, claims 26-28 are drawn to a therapeutic method for kidney diseases, pancreatic diseases or skin diseases, which comprises **concurrently administering** a compound which promotes induction of $CD11b^{+}CD2^{+}$ macrophages and a compound which promotes induction of $CD11b^{-}CD2^{+}$macrophages to a patient.

The inventions listed as Groups I, II, III, IV, V, and VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive

concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

The expression "special technical features" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings. Whether or not any specific technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature", should be considered with respect to novelty and inventive step.

In group I of this instant application, the special technical feature lies in the **mode of screening using lipopolysaccharide** while in group II, the special technical feature lies in the **use of mitomycin rather than lipopolysaccharide** for contacting human PBCs.

In group III of this instant application, the special technical feature lies in the **method of suppression and/or regeneration** of sclerotic lesions **administering a compound** that preferentially increases regeneration-promoting macrophages.

In group IV of this instant application, the special technical feature lies in the therapeutic method **for renal glomerular lesions** while in group V, the special technical feature lies in the therapeutic method **for renal tubulointerstitial lesions**.

In group VI of this instant application, the special technical feature lies in the **concurrent administration of a compound,** which promotes induction of $CD11b^{+}CD2^{+}$ macrophages **and a compound**, which promotes induction of $CD11b^{-}$ $CD2^{+}$macrophages to a patient.

Species Election

This application contains claims directed to more than one species of the generic invention. These species either possess divergent technical properties and/or entail the incorporation of additional agents that are different in physical properties (i.e. granulation involves the addition of hydrophilic components whereas extrusion involves the addition of hydrophobic components). Thus, these species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species listed below do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same special technical feature among the different species.

The species are as follows:

For Group IV:

a) Applicant is required to elect a particular compound out of the group listed in claim 23.

For Group V:

a) Applicant is required to elect a particular compound out of the group listed in claim 25.

For Group VI:

a) Applicant is required to elect a particular compound out of the group listed in claim 28.

b) Applicant is also required to elect a particular disease to be treated out the list below:

1) kidney diseases

2) pancreatic diseases

3) skin diseases

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claims 16-17 and 21-28 are generic.

Applicant is also reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-5 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SJL

10/09/07

Ardin H. Marschel 10/10/10

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER